

Exhibit 4

*State of California ex. rel. Ven-A-Care of the Florida Keys, Inc. v.
Abbott Laboratories, Inc., et al.*

Exhibit to the Declaration of Matthew C. Kilman in Support of
Plaintiffs' Opposition to Mylan's Motion for Partial Summary Judgment

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION**
Washington, DC 20549

FORM 10-K

Annual Report pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934
For the Fiscal Year Ended March 31, 2004

Commission File No. 1-9114

MYLAN LABORATORIES INC.

(Exact name of registrant as specified in its charter)

Pennsylvania
(State of Incorporation)

25-1211621
(IRS Employer Identification No.)

**1500 Corporate Drive
Canonsburg, Pennsylvania 15317
(724) 514-1800**
(Address, including zip code, and telephone number,
including area code, of principal executive offices)

Securities registered pursuant to Section 12(b) of the Act:

Title of Each Class:	Name of Each Exchange on Which Registered:
Common Stock, par value \$0.50 per share	New York Stock Exchange

Securities registered pursuant to Section 12(g) of the Act: None

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. ☐

Indicate by check mark whether the registrant is an accelerated filer (as defined in Rule 12b-2 of the Exchange Act). Yes ☒ No ☐

The aggregate market value of voting stock held by non-affiliates of the registrant as of September 30, 2003, the last business day of the Registrant's most recently completed second fiscal quarter, was \$6,733,207,363, based upon the closing price of the common stock on that date, as reported by the New York Stock Exchange. Shares of common stock known to be owned by directors and executive officers of the registrant subject to Section 16 of the Securities Exchange Act of 1934 are not included in the computation. No determination has been made that such persons are "affiliates" within the meaning of Rule 12b-2 under the Exchange Act.

The number of outstanding shares of common stock of the registrant as of June 1, 2004, was 268,555,780.

DOCUMENTS INCORPORATED BY REFERENCE

Incorporated by reference into Part III, Items 10-14 of this Form are portions of the registrant's Proxy Statement for the 2004 Annual Meeting of Shareholders, which will be filed with the Securities and Exchange Commission within 120 days after the end of the registrant's fiscal year ended March 31, 2004.

MYLAN LABORATORIES INC.

INDEX TO FORM 10-K
For the Fiscal Year Ended March 31, 2004

	<u>Page</u>
<u>PART I</u>	
ITEM 1. Business	3
<u>Overview of Our Business</u>	3
Generic Segment	3
<u>Brand Segment</u>	4
Product Development	5
Generic Product Development	6
Brand Product Development	7
Patents, Trademarks and Licenses	8
Customers and Marketing	9
Competition	9
<u>Product Liability</u>	10
Raw Materials	10
Government Regulation	10
Seasonality	11
Environment	11
Employees	11
Backlog	12
Risk Factors	12
Securities Exchange Act Reports	21
ITEM 2. Properties	21
ITEM 3. Legal Proceedings	22
ITEM 4. <u>Submission of Matters to a Vote of Security Holders</u>	24
<u>PART II</u>	
ITEM 5. <u>Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities</u>	25
ITEM 6. <u>Selected Financial Data</u>	26
ITEM 7. <u>Management's Discussion and Analysis of Results of Operations and Financial Condition</u>	27
ITEM 7A. <u>Quantitative and Qualitative Disclosures About Market Risk</u>	39
ITEM 8. <u>Financial Statements and Supplementary Data</u>	41
ITEM 9. <u>Changes in and Disagreements with Accountants on Accounting and Financial Disclosure</u>	67
ITEM 9A. <u>Controls and Procedures</u>	67
<u>PART III</u>	
ITEM 10. <u>Directors and Executive Officers of the Registrant</u>	68
ITEM 11. <u>Executive Compensation</u>	68
ITEM 12. <u>Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters</u>	68
ITEM 13. <u>Certain Relationships and Related Transactions</u>	68
ITEM 14. <u>Principal Accounting Fees and Services</u>	68
<u>PART IV</u>	
ITEM 15. <u>Exhibits, Financial Statement Schedules, and Reports on Form 8-K</u>	69
Signatures	74
<u>Subsidiaries</u>	
Consent of Independent Public Accounting Firm	
Section 302 Certification of CEO	
Section 302 Certification of CFO	
Section 906 Certifications of CEO and CFO	

Table of Contents

PART I

ITEM 1. Business

Mylan Laboratories Inc. ("the Company" or "Mylan" or "we") is engaged in developing, licensing, manufacturing, marketing and distributing generic and brand pharmaceutical products. The Company was incorporated in Pennsylvania in 1970. References herein to a fiscal year shall mean the fiscal year ended March 31.

Overview of Our Business

We conduct business through our generic ("Generic Segment") and brand ("Brand Segment") pharmaceutical operating segments. For fiscal 2004, the Generic Segment represented approximately 80% of net revenues, and the Brand Segment represented approximately 20% of net revenues. For fiscal 2003 and 2002, the Generic Segment represented approximately 80% and 88% of net revenues, and the Brand Segment represented approximately 20% and 12% of net revenues. The financial information for our operating segments required by this Item is provided in Note 13 to Consolidated Financial Statements under Part II, Item 8, of this Annual Report on Form 10-K.

Prescription pharmaceutical products in the United States ("U.S.") are generally marketed as either brand or generic drugs. Brand products are marketed under brand names through marketing programs that are designed to generate physician and consumer loyalty. Brand products generally are patent protected, which provides a period of market exclusivity during which they are sold with little or no competition. Additionally, brand products may benefit from other periods of non-patent, market exclusivity. Exclusivity generally provides brand products with the ability to maintain their profitability for relatively long periods of time. Brand products generally continue to have a significant role in the market after the end of patent protection or other market exclusivities due to physician and consumer loyalties.

Generic pharmaceutical products are the chemical and therapeutic equivalents of reference brand drugs. A reference brand drug is an approved drug product listed in the U.S. Food and Drug Administration ("FDA") publication entitled *Approved Drug Products with Therapeutic Equivalence Evaluations*, popularly known as the "Orange Book." The Drug Price Competition and Patent Term Restoration Act of 1984 ("Waxman-Hatch Act") provides that generic drugs may enter the market after the approval of an Abbreviated New Drug Application ("ANDA") and the expiration, invalidation or circumvention of any patents on the corresponding brand drug, or the end of any other market exclusivity periods related to the brand drug. Generic drugs are bioequivalent to their brand name counterparts. Accordingly, generic products provide a safe, effective and cost efficient alternative to users of these brand products. Growth in the generic pharmaceutical industry has been driven by the increased market acceptance of generic drugs, as well as the number of brand drugs for which patent terms and/or other market exclusivities have expired.

Generic Segment

We are recognized as a leader in the generic pharmaceutical industry. The Generic Segment consists of two principal business units, Mylan Pharmaceuticals Inc. ("MPI") and UDL Laboratories, Inc. ("UDL"), both of which are wholly owned subsidiaries of Mylan. MPI is our primary generic pharmaceutical research, development, manufacturing, marketing and distribution subsidiary. MPI's net revenues are derived primarily from the sale of solid oral dosage products. UDL packages and markets generic products, either obtained from MPI or purchased from third parties, in unit dose formats, for use primarily in hospitals and other institutions. The Generic Segment is augmented by transdermal patch products which

Table of Contents

are developed and manufactured by Mylan Technologies Inc. ("Mylan Tech"), a wholly owned subsidiary of Mylan.

We obtain new products primarily through internal product development. Additionally, we license or co-develop products through arrangements with other companies. New generic product approvals are obtained from the FDA through the ANDA process, which requires us to demonstrate bioequivalence to a reference brand product. Generic products are generally introduced to the marketplace at the expiration of patent protection for the brand product or at the end of a period of non-patent market exclusivity. However, if an ANDA applicant is first to file an ANDA containing a certification of invalidity, non-infringement or unenforceability related to a patent listed in the "Orange Book" with respect to a reference drug product, that generic equivalent may be able to be marketed prior to the expiration of patent protection for the brand product. Such certification, commonly referred to as a Paragraph IV certification, results in a period of generic marketing exclusivity. This exclusivity lasts for 180 days during which the FDA cannot grant final approval to any other generic equivalent.

We have attained a position of leadership in the generic industry through our ability to obtain ANDA approvals, our uncompromising quality control and our devotion to customer service. We have bolstered our traditional solid oral dose products with unit dose, transdermal and extended release products. We have entered into strategic alliances with several pharmaceutical companies through product development, distribution and licensing agreements that provide us with additional opportunities to broaden our product line.

Mylan manufactures approximately 95% of all doses sold by our Generic Segment. Our product portfolio consists of over 140 generic pharmaceutical products, including approximately 130 in capsule or tablet form in an aggregate of approximately 315 dosage strengths, with 13 extended release products in 27 dosage strengths of which 2 are transdermal patches in 6 dosage strengths. In addition to those products manufactured by Mylan, we are marketing 57 generic products in 102 dosage strengths under supply and distribution agreements with other pharmaceutical companies. At the end of fiscal 2004, Mylan held the first or second market position in new and refilled prescriptions dispensed among all pharmaceutical companies in the U.S. with respect to approximately 70% of the generic pharmaceutical products we marketed, excluding unit-dose products.

Approximately 17%, 20% and 22% of the Generic Segment's net revenues in fiscal 2004, 2003 and 2002, respectively, were contributed by calcium channel blockers, primarily nifedipine. In 2002, antianxiety products, primarily buspirone, represented approximately 22% of net revenues.

The future success of our Generic Segment is dependent upon continued increasing market acceptance of generic products as substitutes for existing products. Additionally, we expect that future growth of our Generic Segment will result from an emphasis on the development or acquisition of new products that may attain FDA first to file status, as well as the pursuit of products that are difficult to formulate or for which the active pharmaceutical ingredient is difficult to obtain. In addition, we intend to continue to seek complementary strategic acquisitions of both companies and products.